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EXAMINER

HARRIS, A

ART UNIT PAPER NUMBER

1642

19

DATE MAILED:

12/18/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
08/973,815

Applicant(s)  
Zentgraf et al.

Examiner  
Alana M. Harris, Ph. D.

Group Art Unit  
1642



☒ Responsive to communication(s) filed on August 1, 2000.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 13 and 14 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 13 and 14 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 18, filed August 1, 2000.

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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**DETAILED ACTION**

***Response to Amendment***

1. Claims 13 and 14 are pending.

Claim 7 has been canceled.

Claims 13 and 14 have been added.

Claims 13 and 14 are examined on the merits.

***Priority***

2. The Examiner thanks Applicant for the clarification regarding the declaration acknowledging the filing of PCT/DE96/01016.

3. The instant application, filed under former 37 CFR 1.60 now recites the necessary reference to prior applications.

***Drawings***

4. The Examiner acknowledges Applicants' request that the objection of the drawings be held in abeyance until allowable subject matter has been identified.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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***Withdrawn Rejections***

***Claim Rejections - 35 U.S.C. § 112***

6. The rejection of claim 7 is under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of Applicants cancellation of the claim.

***Claim Rejections - 35 U.S.C. § 102***

7. The rejection of claim 7 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent #5,830,744 (filed June 6, 1995) is withdrawn in view of Applicants cancellation of the claim.

***Claim Rejections - 35 U.S.C. § 103***

8. The rejection of claim 7 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent # 5,279,823 (filed June 8, 1992), in view of #5,830,744 (filed June 6, 1995) is withdrawn in light of Applicants cancellation of claim.

***New Grounds of Rejection***

***Claim Rejections - 35 U.S.C. § 112***

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

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make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 14 is rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure without complete evidence either that the claimed biological materials are known and readily available to the public or complete evidence of the deposit of the biological materials.

The specification lacks complete deposit information for the deposit of monoclonal antibody 11/78/1 having the deposit number DSM ACC 2211. It is not clear that monoclonal antibodies possessing the identical properties of the claimed monoclonal antibody are known and publicly available or can be reproducibly isolated from nature without undue experimentation.

Exact replication of a cell line is an unpredictable event. Although applicant has provided a written description of a method in the provided laboratory notebook for priming an animal in order to produce antibodies but this method will not necessarily reproduce antibodies which are chemically and structurally identical to those claimed. It is unclear that one of skill in the art could derive antibodies identical to those claimed. Undue experimentation would be required to screen all of the possible antibodies and the hybridomas that produce said antibodies to obtain the claimed antibodies and hybridomas.

Because one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed in the absence of the availability of the claimed antibodies, a suitable deposit of monoclonal antibody 11/78/1 having deposit number DSM ACC 2211 for patent purposes,

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evidence of public availability of the claimed cell lines or evidence of the reproducibility without undue experimentation of the claimed monoclonal antibodies, is required.

Applicant's referral to the deposit of monoclonal antibodies as listed on page 9 of the specification is an insufficient assurance that all required deposits have been made and all the conditions of 37 CFR 1.801-1.809 met.

If the deposits are made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposits have been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State.

11. Claims 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 13 is vague and indefinite because of its improper reference to a SEQ ID Number. The paper sequence listed provided by Applicants reference SEQ ID NO:1 as a nucleic

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acid sequence with 2661 base pairs. However, within the sequence description there is an amino acid sequence. It is not clear as to how claim 13 should read based on the aforementioned facts. Applicants must clarify and submit sequence listing that identifies the nucleic acid and the deduced amino acid, each with their own SEQ ID Number. The metes and bounds of the claim cannot be determined.

b. Claims 13 and 14 are vague and indefinite because it is not clear as to whether the antibody of claim 13 defined as monoclonal antibody 11/78/1 having deposit number DSM ACC 2211 binds the amino acid or the nucleic acid.

*Claim Rejections - 35 U.S.C. § 102*

12. Claim 13 is rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent #5,830,744 (filed June 6, 1995). U.S. Patent #5,830,744 discloses antibodies, as well as monoclonal antibodies that bind to a protein having the amino acid sequence of SEQ ID NO:1. directed against a protein having DNase activity, the same as that claimed (see column 2, lines 31-33 and column 14, lines 47-50). The DNase protein disclosed in U.S. Patent #5,830,744 has the amino acid of SEQ. ID. NO.1 from this instant application. The antibodies listed in patent '744 do not differ in any significant manner to the antibodies claimed. The record does not contain any evidence that the referenced antibodies do not have the inherent properties of the claimed antibody.

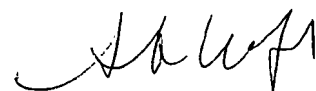
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13. Applicant's amendments necessitated the new grounds of rejection presented in this office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expired **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on Monday through Friday from 6:30 am to 3:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached on (703)308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703)308-0196.

Alana M. Harris, Ph.D.  
Patent Examiner, Group 1642  
December 15, 2000

  
**SHEELA HUFF**  
**PRIMARY EXAMINER**